



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL  
SAFETY AND POLLUTION  
PREVENTION

December 07, 2012

**MEMORANDUM**

**Subject:** Efficacy Review for Baboon; EPA File Symbol 4822-LOR; DP Barcode: D407537

**From:** Ibrahim Laniyan, Ph.D.  
Microbiologist  
Product Science Branch  
Antimicrobials Division (7510P)

A handwritten signature in black ink, likely belonging to Ibrahim Laniyan, is positioned to the right of the "From:" field.

**To:** Demson Fuller / Marshall Swindell PM33  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

**Applicant:** S.C. Johnson & Son Inc.  
1525 Howe Street  
Racine, Wisconsin 53403

**Formulation from the Label:**

<u>Active Ingredient</u>	<u>% by wt.</u>
Hydrogen Peroxide.....	1.4 %
<u>Inert Ingredients</u> .....	98.6 %
Total .....	100.0 %

## I. BACKGROUND

The product, Baboon (EPA File Symbol 4822-LOR), is a new product. The applicant requested to register the product as a disinfectant (bactericide and virucide) and a non-food contact sanitizer for use on hard, non-porous surfaces. This product is proposed as the child of the submitted product Bathroom Spray (EPA File Symbol 89094-G). Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121.

## II. USE DIRECTIONS

The product is designed for disinfecting and sanitizing hard, non-porous surfaces. The proposed label indicates that the product may be used on hard, non-porous surfaces, including: machinery, tools, tables, counters, floors, carts shelves, made of plastic, glass, vinyl, porcelain and stainless steel. Directions on the proposed label provide the following information regarding use of the product:

**To Disinfect:** Spray surface until thoroughly wet. Allow surface to remain wet for 10 minutes and then wipe. For heavily soiled areas, a pre-cleaning is required. Rinse with potable water for food-contact surfaces.

**To Sanitize:** Spray surface until thoroughly wet. Allow surface to remain wet for 30 seconds and then wipe. For heavily soiled areas, a pre-cleaning is required. Rinse with potable water for food-contact surfaces.

## III AGENCY STANDARDS FOR PROPOSED CLAIMS

**Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments:** The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (for spray products), or the AOAC Hard Surface Carrier Test. The tests require that sixty carriers must be tested with each of 3 samples, representing 3 different batches, one of which is at least 60 days old, against *Staphylococcus aureus* ATCC 6538 (for effectiveness against Gram-positive bacteria), and *Pseudomonas aeruginosa* ATCC 15442 (representative of a nosocomial pathogen), [120 carriers per sample; a total of 360 carriers] To support products labeled as "disinfectants", killing on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level. To pass performance requirements when using AOAC Hard Surface Carrier Test, tests must result in killing in 58 out of each set of 60 carriers for *Salmonella enterica* ATCC 10708 and *Staphylococcus aureus* ATCC 6538; 57 out of each set of 60 carriers for *Pseudomonas aeruginosa* ATCC 15442.

**Supplemental Claims:** An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum.

#### IV. BRIEF DESCRIPTION OF THE DATA

**Note:** The tested product lots BS-A-LCL, BS-UA-LCL1, and BS-UA-LCL2 were titrated by ATS Labs on September 14, 2011, and found to have concentrations between 1.27% and 1.28% hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>). These reported tested concentrations are close to the **Lower Certified Limit (LCL) of 1.26%**.

**1. MRID 489716-01: "AOAC Germicidal Spray Method, Test Organisms: *Staphylococcus aureus* (ATCC 6538)" for Baboon (EPA File Symbol 4822-LOR), by Nicole Albert. Study conducted at ATS Labs. Study completion date – October 11, 2012. Project Number A14046.**

This study was conducted against *Staphylococcus aureus* (ATCC 6538). Two lots (Lot Nos. BS-UA-LCL1, and BS-UA-LCL2) of the product, Bathroom Spray, were tested using ATS Labs protocol # LEH15090712.GS.1 (copy provided). The product was received ready-to-use as a trigger spray. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. The product lots were at least 60 days old at the time of testing. Ten (10) glass slide carriers per product lot per microorganism were inoculated with 10 microliters of a 48-54 hour suspension of test organisms incubated at 35-37°C in CO<sub>2</sub>. The carriers were dried at 35-37°C for 38 minutes at 50% relative humidity. Each carrier in a horizontal position was sprayed (3 sprays) with the product at a distance of 4-6 inches from the carrier surface. Each carrier remained in contact with the product for 5 minutes at 21°C and 32% relative humidity. Following exposure, the excess liquid was drained off the carrier. Individual carriers were transferred to 20 mL of Lethen Broth containing 0.1% Sodium Thiosulfate for neutralization and subculturing. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. For the dried colony counts, carrier/neutralizing broth mixtures were vortex mixed. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Note: Protocol amendment reported was reviewed.

#### V. RESULTS

MRID Number	Organism	Contact Time	No. Exhibiting Growth/Total No. Tested		Average Dried Carrier Count (CFU/carrier)
			BS-UA-LCL1	BS-UA-LCL2	
489716-01	<i>Staphylococcus aureus</i>	5 minutes	0/10	0/10	2.55 x 10 <sup>5</sup>

#### VI. CONCLUSIONS

1. The submitted efficacy data (MRID # 489716-01) in conjunction with previously submitted efficacy data, **support** the use of the product, Baboon (EPA File Symbol 4822-LOR), as a disinfectant with bactericidal and virucidal activities against the following microorganisms on hard, nonporous surfaces, when used undiluted, in the presence of a 5% organic soil load for a 5 minutes contact time.

*Staphylococcus aureus*

MRID # 489716-01

*Pseudomonas aeruginosa*  
*Escherichia coli* O157:H7  
*Streptococcus pyogenes*  
Methicillin Resistant *Staphylococcus aureus* – MRSA  
Influenza A (H1N1) virus, Strain A/PR/8/34  
Respiratory syncytial virus, Strain Long

MRID # 487698-10  
MRID # 487698-11  
MRID # 487698-12  
MRID # 487698-13  
MRID # 487698-14  
MRID # 487698-15

Killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Purity controls were reported as pure. Viability controls were positive for growth. Sterility controls did not show growth.

3. Previously submitted efficacy data (MRID # 487698-16) **support** the use of the product, Baboon (EPA File Symbol 4822-LOR), as a non-food contact surface sanitizer at room temperature, against *Staphylococcus aureus* and *Klebsiella pneumoniae* in the presence of a 5% organic soil load for a 30-second contact time.

## VII. LABEL

1. The proposed label claims are **acceptable** regarding the use of the product, Baboon (EPA File Symbol 4822-LOR), as a disinfectant with bactericidal and vivucidal activities for use on hard, non-porous surfaces against the following microorganisms when used undiluted in the presence of 5% organic soil, at room temperature, for a 5-minute contact time.

*Staphylococcus aureus*  
*Pseudomonas aeruginosa*  
*Escherichia coli* O157:H7  
*Streptococcus pyogenes*  
Methicillin Resistant *Staphylococcus aureus* – MRSA  
Influenza A (H1N1) virus, Strain A/PR/8/34  
Respiratory syncytial virus, Strain Long

2. The proposed label claims are **acceptable** regarding the use of the product, Baboon (EPA File Symbol 4822-LOR) as a hard, non-food surfaces sanitizer when used undiluted in the presence of 5% organic soil, at room temperature, for a contact time of 30 seconds.